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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/731,126	12/06/2000	Sheng C. Lou	6755.US.O1	9182

23492 7590 07/16/2003

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EXAMINER
PARKIN, JEFFREY S

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 07/16/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/731,126	LOU ET AL.	
	Examiner	Art Unit	
	Jeffrey S. Parkin, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with th correspondence address --

Period f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *01* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 December 2000* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-28* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Restriction Requirement

35 U.S.C. § 121

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

a. Group I, claim(s) 1-4 and 17-20, drawn to **monoclonal antibody 120A-270**, a hybridoma producing said antibody, and a kit comprising said antibody, classified in class 530, subclass 388.35.

b. Group II, claim(s) 1-4 and 17-20, drawn to **monoclonal antibody 115B-151**, a hybridoma producing said antibody, and a kit comprising said antibody, classified in class 530, subclass 388.35.

c. Group III, claim(s) 1-4 and 17-20, drawn to **monoclonal antibody 117-289**, a hybridoma producing said antibody, and a kit comprising said antibody, drawn to a , classified in class 530, subclass 388.35.

d. Group IV, claim(s) 1-4 and 17-20, drawn to **monoclonal antibody 103-350**, a hybridoma producing said antibody, and a kit comprising said antibody, drawn to a , classified in class 530, subclass 388.35.

e. Group V, claim(s) 1-4 and 17-20, drawn to **monoclonal antibody 115B-303**, a hybridoma producing said antibody, and a kit comprising said antibody, drawn to a , classified in class 530, subclass 388.35.

f. Group VI, claim(s) 1-4 and 17-20, drawn to **monoclonal antibody 108-394**, a hybridoma producing said antibody, and a kit comprising said antibody, drawn to a , classified in class 530, subclass 388.35.

g. Group VII, claim(s) 5-16, drawn to **methods** for the **detection** of **HIV antigens** employing p24/p26-specific monoclonal antibodies, classified in class 435, subclass 7.1 (**see also paragraph 7 below**).

h. Group VIII, claim(s) 21 and 22, drawn to isolated p24/p26 **peptides** (SEQ ID NOS.: **1** and **2**) corresponding to **amino acids 63-89**, classified in class , subclass .

i. Group IX, claim(s) 23 and 24, drawn to isolated p24/p26 **peptides** (SEQ ID NOS.: **3** and **4**) corresponding to **amino acids 151-177**, classified in class , subclass .

j. Group X, claim(s) 24 and 25, drawn to isolated and purified p24/p26 **peptides** (SEQ ID NOS.: **5** and **6**), classified in class , subclass .

k. Group XI, claim(s) 27 and 28, drawn to an **antibody detection method**, classified in class 435, subclass 5.

2. **If Group 7 is elected, a single monoclonal antibody or specific combination of antibodies should also be identified.** As set forth *supra*, each of the identified antibodies constitutes an independent and distinct invention and their use in the antigen detection assay would also constitute independent and distinct inventions. This is **not** a species election.

3. The inventions are distinct, each from the other because of the following reasons:

4. Inventions I-VI are all unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, each of the identified Mabs has a different structure and immunological characteristics (e.g., epitope recognition, binding affinity, etc.) and constitutes an independent and distinct invention. Moreover, because of the structural differences between each antibody separate searches will be required.

5. Inventions I-VI and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially

different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the antibodies of Groups I-VI can be employed in a number of materially different processes such as affinity purification protocols or the generation of anti-idiotypic immunological reagents. Moreover, the detection methodology can employ a materially different product such as a polyclonal antisera generated against a shared epitope.

6. Inventions VIII-X are all unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, each of the identified peptides has a different amino acid sequence and attendant physicochemical and immunological properties. Moreover, because of the structural differences between each peptide, separate searches will be required.

7. Inventions I-VI and VIII-X are all unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, each of the identified groups is directed toward a structurally and functionally different molecule.

8. Inventions VII and VIII-X are all unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, the methodology of Group VII neither requires nor uses the peptides of Groups VIII-X.

9. Inventions I-X and XI are all unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, the methodology of Group XI neither requires nor uses the antibodies or peptides of Groups I-VI and VIII-X. Moreover, the methodologies of Groups VII and XI are directed toward different scientific objectives (antigen detection, antibody detection) and employ different reagents and protocols.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, recognized divergent subject matter, and require separate searches, restriction for examination purposes as indicated is proper.

37 C.F.R. § 1.48(b)

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(I).

Correspondence

11. Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward one of the following Group 1600 fax numbers: (703) 308-4242 or (703) 305-3014. Informal communications may be submitted directly to the Examiner through the following fax number: (703) 308-4426. Applicants are encouraged to notify the

Examiner prior to the submission of such documents to facilitate their expeditious processing and entry.

12. Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (703) 308-2227. The examiner can normally be reached Monday through Thursday from 8:30 AM to 6:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisors, James Housel or Laurie Scheiner, can be reached at (703) 308-4027 or (703) 308-1122, respectively. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Respectfully,

Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1648

11 July, 2003